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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,483	03/23/2007	Robert Michael Buch	CU60828	9640

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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,483	BUCH ET AL.	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *3,8,16,17,19,21-24,27-29 and 47-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,9-15,18,20,25,26 and 30-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-26, 30-33 and 35-46, and the species election of (a) hydrogen peroxide and (b) PVP-alkyl vinyl ether/maleic anhydride in the reply filed on 12/03/2008 are acknowledged. Claims 3, 8, 16, 17, 19, 21-24, 27-29 and 47-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The Examiner inadvertently omitted claim 34 from Group I, accordingly it will be examined with Group I.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little

more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "PVP derivative" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus.* See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical

properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful PVP derivatives generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification does not disclose any species, and therefore is not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" in line 5 of claim 1, and line 19 of claim 7, renders the claims indefinite.

The term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound.

The listing of the polymer system as for example "poly(vinylpyrrolidone)-alkyl vinyl ether/maleic anhydride copolymer" in claim 7 renders the claim indefinite.

It is not clear whether the dissolvable strip is comprised of two separate polymer species, i.e. (1) PVP and (2) alkyl vinyl ether/maleic anhydride copolymer each added to one system, or is comprised of a block copolymer comprised of the two polymer species.

2) Claims 4 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the whitening composition" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 recites the limitation "the bleach" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 7, 9-14, 20, 25, 26, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. (US 2002/0187181).

Godbey et al. teach a device for delivery of one or more actives to a subject comprised of a water-dispersible polymeric carrier, an adhesive, and one or more actives. The active agent is associated with the carrier, adhesive or both (Abstract, [0019] and [0045]). The carrier may be a film and the active agent

may be coated, dissolved into, or otherwise applied to the carrier which is cast into a film and dried [0016], [0019] and [0028]. The invention may be used for dental treatments such as whitening, stain bleaching and stain removal by delivering medicaments such as teeth whiteners, like hydrogen peroxide. Sodium fluoride and other agents for treating soft tissues are other useful medications [0013], [0021], [0047] and [0051]. More than one active agent may be configured within the device to be separated by the carrier, adhesive, or both and allowed to react only when the device is activated by moisture [0044]. Because treatments for the teeth occur in a naturally moist environment, it is desirable to design the invention to completely dissolve or disperse slowly [0048] and [0051]. The device may be configured so that the delivery of active agent is immediate, delayed, prolonged or short lived [0020]. The device is substantially unnoticeable when applied, thin, flexible and conformable enough to avoid causing discomfort while worn [0022] and [0033]. The material used to prepare the carrier may be any of the known natural or synthetic water soluble or water dispersible film forming polymers and oligomers; including cellulose derivatives; starch or starch derivatives; gelatin; polyoxyalkylenes; copolymers derived from vinylic monomers; PVP and PVP derivatives [0024]. Suitable plasticizers, including mixtures of water and alcohols such as glycerin can be used to make the film tougher, more comfortable and to generally improve the handling properties [0026]. The amount of plasticizer is at least 1% by weight [0027]. The solubility properties of the carrier can be adjusted [0029]. The adhesive is water soluble or water dispersible; polymers suitable for the adhesive include polymers

derived from maleic anhydride, methyl vinyl ether, ethyl vinyl ether, and N-vinyl pyrrolidone in amounts from about 10 to about 60% of the adhesive composition [0035] and [0036], i.e. the polymers derived from the vinylic monomers are water soluble or water dispersible. Plasticizers, such as glycerin are included in the adhesive [0039]. The carriers and adhesive layers, both containing active agent, are laminated into tapes, i.e. multilayered strips [0068].

In regards to the claims, although the prior art does not teach the specific embodiment that the 'at least one other polymer" is an alkyl vinyl ether/maleic anhydride copolymer, it does teach that polymers derived from maleic acid and either methyl vinyl ether or ethyl vinyl ether, i.e. vinylic monomers, are water soluble or water dispersible and it also teaches that any water soluble or water dispersible polymer can be used for the carrier. Further, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Therefore, it would have been obvious to combine the copolymer of maleic anhydride and either methyl vinyl ether or ethyl vinyl ether with PVP to produce a polymer system that is water soluble or water dispersible. Further still, the adhesive of the prior art is comprised of polymers derived from monomers of maleic anhydride, methyl vinyl ether and N-vinyl pyrrolidone, it would have been well within the purview of the skilled artisan to use an adhesive comprised of PVP and maleic anhydride/methyl vinyl ether copolymer.

In regards to claims 10 and 11, although the prior art does not teach the percentages by weight of the polymers of the water soluble or water dispersible polymer system, it does teach that the films are cast and dried. Therefore, it can be reasonably assumed that the solvent is evaporated from the film during drying causing the weight content of the polymers in the polymer system to increase from the amount in solution. Further, as discussed above the adhesive layer is comprised of about 60% of polymers derived from monomers of maleic anhydride, methyl vinyl ether and N-vinyl pyrrolidone, i.e. PVP-alkyl vinyl ether/maleic anhydride. Therefore, the strip would be reasonably assumed to be comprised of about 60% to about 95% of a water soluble or water dispersible polymer system comprised of PVP and maleic anhydride/methyl vinyl ether copolymer when considering the amounts of the polymers in both the carrier/film and adhesive which make up the delivery system, i.e. whitening strip.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. as applied to claims 1, 2, 7, 9-14, 20, 25, 26, 30 and 31 above, and further in view of Sagel et al. (US 6,582,708).

Godbey et al. is discussed above.

Godbey et al. does not teach that the whitening strip has a thickness of about 5 μm to about 2000 μm.

Sagel et al. is used as a general teaching and disclose a whitening strip which comprises a peroxide (Abstract, column 3, lines 58-60). The overall

thickness of the delivery system is less that about 1mm (column 9, lines 35-40), i.e. 1000 µm.

At the time of the invention, it would have been obvious to modify the device of Godbey to be less than about 1 mm thick since whitening strips that are known in the art have a less than about 1 mm thickness as taught by Sagel et al.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. as applied to claims 1, 2, 7, 9-14, 20, 25, 26, 30 and 31 above, and further in view of Rudy et al. (US 4,971,782).

Godbey et al. is discussed above.

Godbey et al. do not teach that the whitening agent is encapsulated or dissolves by interaction of the shell with saliva.

Rudy et al. teach that a method of stabilizing peroxide is to provide an edible coating or encapsulation with polymer materials (column 6, lines 40-52). The peroxide can be encapsulated by a water soluble, water dispersible coating, preferably edible (column 3, lines 7-10). The coating should be of a thickness and composition so that it disintegrates during application into the mouth to release peroxide (column 7, lines 11-14). The amount of whitening agent varies from about 1 to about 20% by weight of the composition.

Rudy et al. do not teach a dissolvable whitening strip.

At the time of the invention, it would have been obvious to modify the composition of Godbey et al. to use the encapsulated whitening agent of Rudy et

al. motivated by the desire to stabilize the peroxide until it is placed into the mouth, i.e. comes into contact with saliva.

Claims 4, 15, 18, 27, 32, 34-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. and Rudy et al. as applied to claims 5 and 6 above, and further in view of Perna (US 2003/0228264).

Godbey is discussed above.

Godbey does not teach that the whitening agent is about 2 to about 75% of the whitening composition; the strip is further comprised of a desensitizing compound of claim 18; or a multi-layered strip.

Rudy et al. is discussed above.

Rudy et al. does not teach a multilayer whitening strip.

Perna teaches a teeth whitening system comprising a dissolvable matrix that supports a whitening material which dissolves in the presence of oral fluids (Abstract and [0010]). The dissolvable substrate is a dissolvable matrix composed of suitable dissolvable material [0028]. The matrix can be poured, dried or otherwise formed into a flexible form [0035]. The dissolvable substrate is shaped into desired solid form by a conventional technique such as extruding and may be shaped into rectangles for application to multiple teeth [0045]. The whitening material may be mixed with the dissolvable matrix [0011]. The whitening material may coat one side of the dissolvable substrate [0032]. Multiple layers of whitening materials may be interspersed between layers of a dissolvable composition [0035]. i.e. multilayered. The dissolution rate of the

matrix can be controlled [0036]. The whitening material may be any suitable whitening material and may utilize hydrogen peroxide or hydrogen peroxide precursor such as sodium percarbonate; a suitable concentration of peroxide in the apparatus ranges from 0.25% to approximately 5% by weight [0048], [0053], [0054] and [0074]. Hydrogen peroxide and glyceryl triacetate are used in the dissolvable matrix to rapidly generate peroxyacid [0076]. Materials that can be incorporated into the whitening material include desensitizing agents such as potassium nitrate and potassium citrate [0064].

Perna does not teach that the dissolvable layer of a single layered device or that the multiple layers are comprised of PVP-alkyl vinyl ether copolymer.

At the time of the invention it would have been obvious to modify the invention of Godbey et al. to the form of a multilayer device, since dissolvable multilayer devices for teeth whitening are known in the art, as taught by the secondary reference.

In regards to claim 40, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Therefore, it would have been obvious to use both hydrogen peroxide and a hydrogen peroxide precursor such as sodium percarbonate as the whitening material.

In regards to claims 43 and 44, the prior art teaches that the dissolution of the films may be adjusted by the addition of a water insoluble polymer; and that

the device can be configured to provide immediate, delayed, prolonged or short lived delivery of the active agent. Therefore, it would have been obvious to modify the multiple film layer device suggested by combining Godbey et al. and Perna to have that have layers of different dissolution rates by varying the composition of the films to include different amounts of a water insoluble polymer. By producing multilayered strips comprised of films with different dissolution rates, the delivery of hydrogen peroxide is delayed or prolonged, since one strip dissolves and delivers active before the other begins to dissolve. Further, the multilayered strips comprised of films of different dissolution rates provide directional dissolution of the multilayered strip, i.e., a layer which is contact with the surfaces of the teeth and formulated to dissolve faster, will dissolve and delivery the whitening agent to the teeth instead of toward an outer layer.

In regards to claims 45 and 46, it would have been obvious to modify the multilayer strip suggested by combining Godbey et al., Rudy et al. and Perna by further adding a layer of encapsulated whitening agent since Perna teaches multilayer whitening devices and that the layers can be coated with whitening material and Rudy et al. teaches that encapsulation of whitening materials helps to stabilize them until placement into the oral cavity.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612